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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,244

Applicant(s)

BHADRA ET AL.

Examiner

George R Evanisko

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 and 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2-4, the claims are vague since they are not claiming any method steps.

In claims 4 and 14, the claims are vague and conflict with claims 1 and 11 since claims 4 and 14 use a surface electrode but claims 1 and 11 have the electrode “coupled” or “applied” to a sacral dorsal root.

In claim 11, “applied to a” ventral root or sacral root is vague since it sounds as if there is a positive connection to the body. Apparatus claims can not claim a connection to the body. It is suggested to use “adapted to be applied”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 5, 8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Brindley (3870051). Although Brindley is coupled to the complete sacral nerve, he still is coupled to both the dorsal and ventral roots since both are located in the sacral nerve and since he uses different stimulation parameters to affect both.

Claims 1-3, 8 and 11-13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fang et al (5199430).

Claims 1, 8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanagho et al (EP 0245547). As stated on page 9, line 45, the pulses may "overlap".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brindley (or Fang et al or Tanagho).

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Brindley (or Fang et al or Tanagho) discloses the claimed invention except for the surface electrode for stimulating the sacral nerve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sacral nerve stimulation system as taught by Brindley (or Fang et al or Tanagho), with the use of an external surface electrode to stimulate the sacral nerve since it was known in the art that sacral stimulation systems use external surface electrodes to stimulate the sacral nerve to provide a non-invasive way of effectively delivering the stimulation.

Claims 5-7, 9, 10, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fang et al.

Fang discloses the claimed invention and that the pulse parameters may be adjusted to excite/activate or block different nerves except for the particulars of the stimulation pulse parameters, such as quasi-trapezoidal or rectangular pulse trains at 20 Hz (claims 5, 6, and 15), an intermittent pulse train at 20 Hz on and off for 1 second each (claims 7 and 16), the second electrode pulse having a nominal amplitude of less than 1 ma and a pulse duration of 10-100 usec (claims 9 and 18), and the first electrode pulse having a nominal amplitude of 1 ma and a pulse duration of 350-500 usec (claims 10 and 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pulse parameters of the nerve cuff electrodes as taught by Fang, with the particular pulse parameters of claims 5-7, 9, 10 and 15-18, since it was known in the art that cuff electrodes used to stimulate different nerves apply different and particular pulse parameters, such as the pulse parameters in claims 5-7, 9, 10, and 15-18, so that the nerves can be effectively stimulated to activate or block particular

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diameter nerves and since it is known in the art that different electrode sizes and spacing require different signals to activate or block different nerves.

In addition, Fang provides a clear suggestion that the pulse parameters can be modified to activate or block different nerve fibers. The determination of the most appropriate stimulation parameters, such as the particular pulse parameters of claims 5-7, 9, 10, and 15-18, by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the medical art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

George R Evanisko
Primary Examiner
Art Unit 3762

2/24/03

GRE
February 24, 2003